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10/574,934	04/07/2006	Satomi Miyata	MIYATA 6	5550

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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1611	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/574,934	MIYATA ET AL.	
	Examiner	Art Unit	
	Isis A. Ghali	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 March 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *17-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *04/28/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicants' amendment and request for RCE, both filed 03/19/2009; and IDS filed 04/28/2009.

Claims 1-16 have been canceled.

Claims 17-19 previously presented. Claims 20-30 currently added.

Claims 17-30 are pending and included in the prosecution.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 03/19/3008 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 24 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection. The claim recites "sour agents, extracts, saccharides". The claim further recites "derivatives thereof".

The specification gives no guidance to one of ordinary skill in the art regarding any of the claimed expression/terms. The specification does not describe any of "sour agents, extracts, saccharides". The recitation of the expressions "sour agents, extracts, saccharides" without partial or complete description of any of the expressions does not convey to one of ordinary skill in the art that applicants were in possession of the claimed subject matter. Further, "other ingredients" are recited by claim 24 without any correlation to the claimed products "food, pharmaceutical, cosmetic, etc.", does not meet the written description requirement for the claimed method as one of ordinary skill in the art could not recognize or understand the "other ingredients" from the mere recitation of broad expressions as "sour agents, extracts, saccharides". It is not clear which other ingredient suitable for which of the claimed products: food, feed, cosmetic, etc. Each of the recited term/expression can be myriad of ingredients. What kind of extract applicant intended to claim? Is it a plant extract, microbial extract, animal extract,

etc? Similarly, what are the sour agents and what are the saccharides that are suitable to practice the claimed invention, and further why one would add sour agent to a composition as a cosmetic for example? Claims employing limitation at the point of novelty, such as applicants', neither provide those elements required to practice the inventions, nor "inform the public" during the life of the patent of the limits of the monopoly asserted. The claimed expressions could encompass myriad of ingredients and applicants claimed expression represents only an invitation to experiment regarding possible ingredients and their combination with the product as food, cosmetic, etc.

To satisfy the Written description requirement, applicant must convey with reasonable clarity to one skilled in the art, as of the filing date that applicant were in possession of the claimed invention. *Vas-Cath Inc. v Mahurkar*, 19 USPQ 2d 1111. The invention is, for purpose of the "written description" inquiry, what ever is now claimed (see page 1117). The specification does not clearly allow person of ordinary skill in the art to recognize that [he or she] invented what is claimed (see *Vas-Cath* at page 116). One cannot describe what one has not conceived. See *Fiddes v Baird*, 30 USPQ2d 1481, 1483. In *Fiddes*.

The test for determining compliance with the written description requirement is whether the disclosure of the application as originally filed reasonably conveys to one skilled in the art that the inventor had the possession at the time of the later claimed subject matter, rather than the presence or absence of literal support in the specification for the claimed language. See In re Kaslow, 707 F 2d 1366, 1375 (Fed. Cir. 1983). See MPEP 2163.06.

The written description requirement prevents applications from using the amendment process to update the disclosure in their disclosures (claims or specification) during the pendency before the patent office. Otherwise applicants could add new matter to their disclosures and date them back to their original filing date, thus defeating an accurate accounting of the priority of the invention. See 35 USC 132. The function of description requirement is to ensure that the inventor had possession, as of filing date of the application relied on, the specific subject matter claimed by him. See *Genetech*, 108 F 3d 1361, 1365 (Fed. Cir. at 1366, 78, 1999).

Additionally, the term "derivative" as recited in line 8 of instant claim 24 does not comply with the written description requirement.

A genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. It the genus has substantial variance, the disclosure must describe a sufficient number of species to reflect the variation within that genus. See MPEP 2163. Although the MPEP does not specifically define what constitutes a representative number of species, courts have indicated what does not constitute same. See, e.g., *In re Gostelli*, 10 USPQ 2d 1614, 1618 (Fed. Cir. 1989), holding that the disclosure of two compounds within a subgenus did not adequately describe such subgenus.

As outlined in *Univ. of Calf. V. Eli Lilly*, 43 USPQ 2d 1398, 1406 (Fed. Cir. 1997), a description of a genus can comprise a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. This is analogous to enablement of a genus under Section 112, Para. 1, by showing the

enablement of a representative number of species within the genus. Mere indistinct terms (here the word "derivative"), however, may not suffice to meet the written description requirement.

The instant specification does not describe specific "derivative[s]" of ascorbic acid as "other ingredient" in the product that can be food, cosmetic, fee, etc., other than the main component of the claimed composition comprising "glucoside or glycoside derivative of L-ascorbic acid. That listing of two species is far narrower in scope than the broad genus "derivative", and claims 17-30 fail to recite any structural features common to the members of that genus which would constitute a substantial portion of the same. Accordingly, the term "derivative" as used currently by instant claims is deemed so indistinct that it fails to reasonably convey to one skilled in the art that applicant was in possession of a representative number of species within that genus.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 21, 22, 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 21 and 22 recite the limitation "said L-ascorbic acid and/or its derivative". There is insufficient antecedent basis for this limitation in the claim. The claims depend on claim 17 that specifically recites "a saccharide derivative of L-ascorbic acid"

Claim 24 failed to further limit the subject matter of a previous claim because claim 17 has limited ascorbic acid to "**a** saccharide derivative of L-ascorbic acid" and claim 24 broadens the scope by reciting "L-ascorbic acid and derivatives thereof". Claim 17 is limited to only one ascorbic acid and is directed to a saccharide derivative.

Claim 24 is confusing as it recites "ascorbic acid or derivatives thereof", is it the same L-ascorbic acid as claimed by claim 17, or the composition further comprises another ascorbic acid derivative?

Claim 24 further repeats the member "viscosity imparting agent" twice in the Markush group.

The expressions "sour agents", "extracts", and "saccharides" recited by claim 24 do not set forth the metes and bounds of the claim. Recourse to the specification does not define the expressions.

Further, claim 24 recites "derivatives thereof" and the 10th edition of the "Merriam-Webster's Collegiate Dictionary" (Merriam-Webster Incorporated: Springfield, Massachusetts, 1993, pp 311) defines "derivative" as, "a chemical substance related structurally to another substance and theoretically derivable from it." Therefore, the definition of derivative in the Merriam-Webster Collegiate Dictionary does not shed light on what Applicants' intended for the meaning of a derivative.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

7. Claims 17-25, 27-30 are rejected under 35 U.S.C. 102(a) as being anticipated by JP 2003-171290 ('290) as evident by JP 10-147514 ('514) or JP 09-315928 ('928).

JP '290 discloses method for producing collagen production potentiator capable of continuously exhibiting action of potentiating the collagen production by using composition comprising L-ascorbic acid and royal jelly as active ingredient (abstract; paragraph 0008). The L-ascorbic acid is L-ascorbic acid 2-glycoside including L-ascorbic acid 2-glucoside (paragraph 0011). The composition comprising by weight 0.001 to 20% of L-ascorbic acid derivative or royal jelly (paragraph 0019), this disclosure of the reference implied that the royal jelly can be present in the same amount as the L-ascorbic acid derivative, and this meets the limitation of claim 22 that the royal jelly is present in an amount up to one part of the ascorbic acid. JP '290 disclosed that the composition can be a cosmetic, food, quasi drug or feed (claim 10, paragraph 0019). The composition further comprises antioxidant, thickeners, sugar and sugar alcohol, gums, water, alcohol, amino acid, vitamin, mineral flavor, emulsifier, seasoning, spices (paragraphs: 0015-0020). Royal jelly inherently contains 10-hydroxy-2-decenoic acid as evident by the disclosure of JP '514 as it discloses that 10-hydroxy-2-decenoic acid is an active ingredient of royal jelly (Problem to be solved; paragraphs 0005, 0012). Inherency of royal jelly content of the claimed fatty acids is further evident by JP '928 that discloses compounds of royal jelly origin comprising 10-hydroxy-2-

decenoic acid, decanoic acid, 2-decenoic acid, sebacic acid (abstract; paragraphs 0007; claims 1 and 2).

The limitations of claims 17-25, 27-30 are met by JP '290.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over JP 2003-171290 ('290) as evident by JP 10-147514 ('514) or JP 09-315928 ('928) by them selves or further in view of JP 2000-159656 ('656), its translated abstract provided by applicant in the IDS filed 04/28/2009, and full translated document is provided by the examiner attached to this office action.

The teachings of JP '290 are previously discussed as set forth in this office action.

JP '290 further teach cosmetics that containing mucopolysaccharides such as hyaluronic acid have been developed as cosmetic for aging prevention in order to secure the moistness of the skin (paragraph 0006).

Therefore, as admitted by JP '290, at the time of the invention it was known to include hyaluronic acid in cosmetic composition. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to include hyaluronic acid in the composition comprising saccharide derivative of L-ascorbic acid and royal jelly. One would have been motivated to do so because JP '290 teaches that hyaluronic acid is known to be included in cosmetic for aging prevention in order to secure the moistness of the skin. One would reasonably expected formulating composition comprising saccharide derivative of L-ascorbic acid, royal jelly and hyaluronic acid,

wherein the composition potentiates the production of collagen and prevents aging and further secures the moistness of the skin.

Further, JP '656 teaches cosmetic composition having collagen synthesis accelerating effect, excellent in stability and provides cosmetic excellent in wrinkles prevention (abstract). The composition comprises ascorbic acid derivative and hyaluronic acid (paragraphs 0010, 0017, 0018).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide composition comprising saccharide derivative of L-ascorbic acid and royal jelly to accelerate collagen formation as disclosed by JP '290, and further add hyaluronic acid taught by JP '656 o the composition. One would have been motivated to do so because JP '656 teaches that composition comprising hyaluronic acid and ascorbic acid derivatives provides collagen synthesis accelerating effect, excellent in stability and provides cosmetic excellent in wrinkles prevention. One would reasonably expected formulating composition comprising saccharide derivative of L-ascorbic acid, royal jelly and hyaluronic acid, wherein the composition have collagen synthesis accelerating effect and excellent in wrinkles prevention, meanwhile is table composition.

12. Claims 17-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of JP 2000-159656 ('656), its translated abstract provided by applicant in the IDS filed 04/28/2009, and full translated document is provided by the examiner attached to this office action, combined with JP 09-030921 ('921) and further combined

with JP 09-315928 ('928), translation of both is provided by the examiner attached to this office action.

Applicant's claims

Claim 17 as currently presented is directed to method for enhancing collagen production comprising administering a composition comprising (i) a saccharide derivative of L-ascorbic acid and (ii) a fatty acid to a living body.

Determining the scope and contents of the prior art (MPEP*§ 2141.01)*

JP '656 teaches cosmetic composition having collagen synthesis accelerating effect, excellent in stability and provides cosmetic excellent in wrinkles prevention (abstract). The composition comprises L-ascorbic acid derivative, oils and fatty acids and hyaluronic acid (paragraphs 0010, 0017, 0014, 0018). The composition further comprises thickener, perfumes, water (paragraphs 0018, 0046).

JP '921 teaches composition for treating the dermal stains or aging by using specific derivatives of L-ascorbic acid (abstract). L-ascorbic 2-glucoside is preferred derivative of ascorbic acid and is present in the composition in an amount ranging from 0.01 to 20% (solution). The composition further comprising antioxidant rutin derivative (abstract; paragraph 0017).

JP '928 teaches compounds of royal jelly origin comprising 10-hydroxy-2-decenoic acid, decanoic acid, 2-decenoic acid, sebacic acid (abstract; paragraphs 0007; claims 1 and 2). The reference teaches beautifying cosmetic comprising 1-20% of these

compounds from royal jelly origin as they inhibit tyrosinase activity to control generating melanin and provide skin whitening cosmetic (abstract; paragraphs 0001, 0007, 0013). JP '921 teaches that royal jelly is widely used as health food and does not have skin irritation (paragraph 0010).

Ascertaining the differences between the prior art and the claims at issue, and resolving the level of ordinary skill in the pertinent art (MPEP § 2141.012)

Although JP '656 teaches the combination of ascorbic acid and fatty acid, however, the reference does not explicitly teach the saccharide derivative of L- ascorbic acid as required by claim 17 and 20. JP '656 does not explicitly teach that fatty acid are derived from royal jelly as required by claim 18 and 19, or the amount of L-ascorbic acid and fatty acid as claimed by claims 21-22. JP does not teach the composition given as a food as claimed by claims 28 and 30.

However, at the time of the invention it was know by the art to accelerate the production of collagen by using combination of L-ascorbic acid derivative and fatty acid as disclosed by JP '656. The art further recognized L-ascorbic acid 2-glucoside as a preferred L-ascorbic acid derivative to treat dermal aging, and further recognized its amount as disclosed by JP '921. Fatty acids derived from royal jelly were known to be used for cosmetic purposes as beautifying agent and were further known to be used as food as disclosed by JP '928.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to accelerate collagen synthesis effect by using cosmetic

composition comprises L-ascorbic acid derivative and fatty acids that provides cosmetic excellent in wrinkles prevention as taught by JP '656, and replace L-ascorbic acid derivative by 0.01-20% L-ascorbic 2-glucoside as disclosed by JP '921. One would have been motivated to do so because JP '921 teaches that composition comprising 0.01 to 20% of L-ascorbic 2-glucoside treats dermal stains or aging and further teaches that L-ascorbic 2-glucoside is preferred derivative of ascorbic acid. One would have reasonably expected accelerated collagen synthesis by using cosmetic composition comprising 0.01-20% L-ascorbic 2-glucoside and fatty acid wherein the composition successfully treats skin aging and staining. Additionally, it would have been obvious to one having ordinary skill in the art at the time of the invention to accelerated collagen synthesis by using cosmetic composition comprising L-ascorbic 2-glucoside and fatty acid as taught by the combination of JP '656 and JP '921, and further replace the fatty acid by fatty acids extracted from royal jelly as taught by JP '928. One would have been motivated to do so because JP '928 teaches that fatty acids of royal jelly origin do not cause skin irritation and control generating melanin and provide skin whitening cosmetic. One would have reasonably expected accelerated collagen synthesis by using cosmetic composition comprising L-ascorbic 2-glucoside and fatty acid derived from royal jelly wherein the composition successfully treats skin aging and staining without skin irritation.

It would have been obvious at the time of the invention to provide composition comprising royal jelly as food or as cosmetic as disclosed by JP '928.

Regarding the amount of royal jelly fatty acids, one having ordinary skill in the art would have been able to determine the amount and its ratio to the ascorbic acid based on the specific desired effect.

"It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose .... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted) (Claims to a process of preparing a spray- dried detergent by mixing together two conventional spray-dried detergents were held to be prima facie obvious.).

Resolving the level of ordinary skill in the pertinent art (MPEP *§ 2141.012)*

It would have been obvious to one of ordinary skill in the art at the time of the invention, and in view of the disclosure of the prior art to accelerate the synthesis of collagen using the claimed ingredients. The invention as a whole is taught by the combined teaching of the prior art, and considered prima facie obvious in the meaning of 35 USC § 103 (a).

Response to Arguments

13. Applicant's arguments with respect to claims 17-30 have been considered but are moot in view of the new ground(s) of rejection.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

IG

/Isis A Ghali/
Primary Examiner, Art Unit 1611